

REMARKS

Claim Status

Claims 1-53, 56, and 64-77 are pending in the instant application. With this amendment, claims 54, 55, and 57-63 have been cancelled, claims 1, 6-9, 12-15, 17, 18, 20-22, 27, 35, 37, 41-46, and 56 have been amended, and new claims 65-77 have been added. Support for the claim amendments and new claims can be found throughout the specification and claims as originally filed, including, for example, at page 32, line 29, to page 33, line 21; and page 33, lines 18-21.

Claims 6-9, 12, 13, 15, 17, 18, 20-22, 35, 37, 42-45, and 56 have been amended solely to ensure correct antecedent basis for claim terms/phrases and the amendments are not intended to change the claim scope. The preambles of claims 1, 14, 27, 41, and 46 have been amended as suggested by the Examiner during the telephonic Interview of November 25, 2008, to over the 35 U.S.C. § 101 rejection. The preamble claim amendments are not intended to change the scope of the system and method claims, since the claims already had hardware limitations (*e.g.*, the sample carriers).

No new matter is added by the amendment of the claims. Accordingly, entry into the instant application is proper and respectfully requested.

Examiner Interview

Applicants and their undersigned representative thank Examiner Harrell for the helpful and courteous interview on November 25, 2008. During the interview, the pending 35 U.S.C. § 101 and 35 U.S.C. § 112, second paragraph, rejections were discussed and the Examiner indicated that the rejections could be overcome by (i) amending the method claims to recite “executed on hardware”; (ii) amending the system claims to recite “hardware”; and (iii) amending the software claims to recite “computer program product embodied on a hardware computer-readable medium”. In addition, the Layne reference (US Patent 5,968,731) was discussed with regard to the 35 U.S.C. § 102(b) rejection set forth in the Office Action. In particular, Applicants pointed out that the plastic tubes disclosed in Layne were not a suitable sample storage medium operative for long-term storage of biological samples in desiccated form. In addition, Applicants pointed out that the plastic tubes disclosed in Layne were not porous.

Double Patenting

Claims 1–64 are rejected on the ground of nonstatutory obviousness-type double patenting as being allegedly unpatentable over claims 1–36 of U.S. Patent No. 7,142,987. Filed concurrently with this amendment is a Terminal Disclaimer relating to U.S. Patent No. 7,142,987, which is being submitted on behalf of GenVault Corporation, the assignee of 100% of Applicant’s interest in the present application. The filing of this Terminal Disclaimer obviates the present nonstatutory obviousness-type double patenting rejection. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

Claims 1–64 are also rejected on the ground of nonstatutory obviousness-type double patenting as being allegedly unpatentable over claims 1–40 and 58–69 of copending Application No. 10/007,355. Applicant submits that Application No. 10/007,355 is currently pending, subject to 35 U.S.C. § 102(e) rejections, and was filed on *the same date* as the present application. Under such circumstances, a nonstatutory obviousness-type double patenting rejection should be withdrawn, since the issue of double patenting can be raised in Application No. 10/007,355 in the event that claims in that application become otherwise allowable. *See* MPEP 804 I.B.1 (noting that, in situations where a nonstatutory obviousness-type double patenting rejection has been issued in light of a co-pending application and is the only rejection remaining, while the co-pending application remains rejected on other grounds, the nonstatutory obviousness-type double patenting rejection should be withdrawn unless the co-pending application has an earlier filing date). Accordingly, Applicant respectfully requests that this rejection be withdrawn.

Claims 1–64 are also rejected on the ground of nonstatutory obviousness-type double patenting as being allegedly unpatentable over claim 1–64 and 86–117 of copending Application No. 10/150,771, and claims 1–2, 4–11, 13–16, 35–42 and 44–51 of copending Application No. 10/252,352. Applicant submits that Application Nos. 10/150,771 and 10/252,352 are currently pending, subject to rejections based on 35 U.S.C. §§ 102(b), 102(e), 103(a), and/or 112, and were both filed *after* the filing date of the present application. Under such circumstances, nonstatutory obviousness-type double patenting rejections should be withdrawn. *See* MPEP 804 I.B.1 (“If a ‘provisional’ nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed

application is rejected on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer.”). Accordingly, Applicant respectfully requests that this rejection be withdrawn.

35 U.S.C. § 101

Claims 1-64 stand rejected under 35 U.S.C. § 101 as allegedly encompassing non-statutory subject matter. According to the Office Action at paragraph 13, the claimed methods encompass software or program per se equivalents, while the system claims encompass only software or program per se equivalents.

Applicants submit that the claimed methods and systems include limitations that are patently hardware limitations, such as the claimed sample carriers. Nevertheless, solely for the purpose of expediting prosecution of the present application, Applicants have amended the claims as suggested by the Examiner to overcome this rejection. Accordingly, Applicants respectfully request that this rejection be withdrawn.

35 U.S.C. § 112, Second Paragraph

Claims 1-64 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. According to the Office Action at paragraph 16, the claims provide no clear recital of actual hardware, so one cannot clearly ascertain whether the claims encompass only hardware, only software, or a combination thereof.

Applicants submit that the claimed methods and systems include limitations that are patently hardware limitations, such as the claimed sample carriers. Nevertheless, solely for the purpose of expediting prosecution of the present application, Applicants have amended the claims as suggested by the Examiner to overcome this rejection. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Claims 1-64 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. According to the Office Action at paragraph 15, the claims lack clear antecedent basis with respect to various terms.

Applicants have amended the claims to correct all possible instances of unclear antecedent basis. Accordingly, Applicants respectfully request that this rejection be withdrawn.

35 U.S.C. § 102(b)

Claims 1-64 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Layne et al. (U.S. Patent 5,968,731). According to the Office Action at paragraph 20, Layne discloses a method of providing biological analyses to a remote client, wherein the array of test tubes used in the methods read upon the sample carrier and sample nodes of the present application.

Applicants respectfully submit that Layne fails to anticipate the presently claimed invention because Layne does not disclose each and every limitation of the pending claims. Layne is directed to automated assays for detecting infectious diseases such as HIV. The assays use standard laboratory test tubes arrayed in standard multi-well formats. To the extent that the Office Action considers test tubes of Layne as the “sample nodes” of the present invention, applicants respectfully submit that such is not the case. The assays are liquid-based assays and, thus, the test tubes of Layne are used for holding liquids to conduct assays without leakage. In contrast, the present invention uses sample nodes reversibly attached to sample carriers to store samples (*e.g.*, biological samples) in archives. The samples are stored in desiccated form and, accordingly, the sample nodes comprise sample support media (*e.g.*, porous sample support media, such as paper, etc.) constructed and operative to contain biological samples in desiccated form for long-term storage.

When a liquid biological sample is applied to the sample nodes of the present invention, the sample is absorbed and the aqueous portion of the sample evaporates, such that biomolecules in the sample (*e.g.*, nucleic acids, proteins, etc.) are contained within the sample support medium. Significantly, because the test tubes of Layne hold, rather than absorb, liquid samples, they do not provide a sample support medium capable of containing a sample for long term storage. Moreover, these standard test tubes designed for holding samples is not suitable for storage and archiving of biological samples in desiccated form because they can not protect the sample from degradation during long term storage.

Therefore, persons skilled in the art would readily understand that the test tubes of Layne are not sample nodes or sample support media of the present invention. Consistent with Layne’s lack of disclosure of sample support media constructed and operative to contain biological molecules in desiccated form for long-term storage, Layne also lacks a disclosure of sample archives. Rather, Layne is simply focused on automated assay testing of samples.

For at least the foregoing reasons, Layne fails to anticipate the present invention. Accordingly, Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

In light of the above amendments and remarks, Applicant respectfully submits that claims 1-53, 56, and 64-77 satisfy all the criteria for patentability and are in condition for allowance. Applicant requests that the Examiner reconsider this application with a view towards allowance and solicits early passage of claims 1-53, 56, and 64-77 to issuance. The Examiner is invited to call the undersigned attorney, if a telephone call could help resolve any remaining items.

Pursuant to 37 CFR § 1.136(a)(3), the Commissioner is hereby authorized to charge all required fees, including fees under 37 CFR § 1.17 and all required extension of time fees, or credit any overpayment, to Deposit Account No. 50-1283.

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Respectfully submitted,

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